510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	January 16 , 2013
Contact Person:	Fang-Yuan Ho Manager, Regulatory Affairs
Proprietary Name:	U2 Hip System, Expanded Indications for Use
Common Name:	Total hip prostheses
Device Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis under 21CFR 888.3358 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	LPH, JDI, MEH
Predicate Device:	1. "UNITED" U1 Hip System (K994078) 2. "UNITED" U2 Hip Stem, Ti porous coated (K003237) 3. "UNITED" U2 Acetabular Cup and Femoral Head (K022520) 4. "UNITED" U2 Acetabular Component (K050262) 5. "UNITED" U2 Hip Stem, Ti Plasma Spray (K062978) 6. "UNITED" U2 Hip System (K111546) 7. "UNITED" U2 Acetabular Cup, Plasma Spray (K121777) 8. "UNITED" Femoral Heads, +2.5 & +7.5 mm Offset (K122504)

Device Description:

There are two purposes in current submission, the fist one is to expand the Indications for Use of two cleared products: U2 Hip System (K111546) and Femoral Heads, +2.5 & +7.5 mm Offset (K122504), which have been expanded to a population with similar demographic, diagnosis and prognosis as the original. The second purpose of this submission is to reword the statement of Indications for Use of six cleared "UNITED" hip products including U1 Hip System (K994078), U2 Hip Stem, Ti porous coated (K003237), U2 Acetabular Cup and Femoral Head (K022520), U2 Acetabular Component (K050262), U2 Hip Stem and Ti Plasma Spray (K062978) and U2 Acetabular Cup, Plasma Spray (K121777). Through this submission, the Indications for Use of above listed devices are unified as one version, and the components, materials, design, processing methods, sterilization methods, biocompatibility, safety and effectiveness of above listed devices are unchanged by this submission.

Indications for Use:

This device is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed;
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.

This device is a single use implant and intended for cementless use only except cemented stem which is designed for cemented use only.

Basis for Substantial Equivalence:

The components, design, materials, packaging materials and sterilization method of U2 Hip System- Expanded Indications for Use are identical to cleared predicate devices:

1. "UNITED" U1 Hip System (K994078)
2. "UNITED" U2 Hip Stem, Ti porous coated (K003237)
3. "UNITED" U2 Acetabular Cup and Femoral Head (K022520)
4. "UNITED" U2 Acetabular Component (K050262)
5. "UNITED" U2 Hip Stem, Ti Plasma Spray (K062978)
6. "UNITED" U2 Hip System (K111546)
7. "UNITED" U2 Acetabular Cup, Plasma Spray (K121777)
8. "UNITED" Femoral Heads, +2.5 & +7.5 mm Offset (K122504)

The only difference between the proposed and predicate devices is the integration of Indications for Use. The submitted indications are substantially equivalent to the predicate products and do not affect the functional effectiveness and safety.

Besides, the indications are substantially equivalent to legally marketed "WRIGHT" STEM Hip Replacement System (K021346), "HOWMEDICA" Stryker Modular Hip System (K071082) and "BIOMET" Medallion Modular Hip System (K041850) for total hip replacement. In the other hand, for bipolar hip replacement, the indications of current submission are identical to "UNITED" U1 Hip System-Bipolar (K050269) and "UNITED" U2 Bipolar Implant (K101670), and are also equivalent to "Smith & Nephew" Global Bipolar System (K023743) and "BIOMET" RingLoc® Bi-Polar Acetabular Component (K051569).

Summary of Technologies

The technological characteristics (design, materials, packaging materials and sterilization method) of the U2 Hip System- Expanded Indications for Use are identical

to the predicate products.

Non-Clinical Testing

Non-clinical laboratory testing is not provided as a basis for substantial equivalence.

Clinical Testing

None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 6, 2013

United Orthopedic Corporation
% Fang-Yuan Ho
Regulatory Affairs, Manager
No. 57, Park Avenue 2, Science Park
Hsinchu 300
Taiwan

Re: K130149
Trade/Device Name: U2 Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, MEH
Dated: March 8, 2013
Received: March 13, 2013

Dear Fang-Yuan Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K130149 (pg 1/1)

Device Name: U2 Hip System, Expanded Indications for Use

Indications for Use:

This device is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed;
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.

This device is a single use implant and intended for cementless use only except cemented stem which is designed for cemented use only.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth M Frank -S

Division of Orthopedic Devices